

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Reformation Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(e))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Q1P/E 1449
JAN 11 2006
U.S. PATENT & TRADEMARK OFFICE

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
AA	AA	4,952,402	08/28/1990	Sparks et al.			
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation
							Yes
	AL						
	AM						
	AN						
	AO						
	AP						

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AQ	
	AR	
	AS	
	AT	

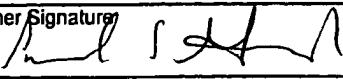
Examiner Signature <i>AL JAH</i>	Date Considered <i>2/3/06</i>
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified) 10/100 NOV 9 2004 FAC 2007 CFR 1.56(b))		U.S. Department of Commerce Patent and Trademark Office		Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.			
		Filing Date July 3, 2003		Group Art Unit 1616	

U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate

Foreign Patent Documents or Published Foreign Patent Applications							
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation
							Yes No
	1	AU 714998	11/19/1997	Australia			
Sta	2	CA 2036844	08/23/1991	Canada			
Sta	3	CA 2136704	05/28/1995	Canada			
Sta	4	EP 0655237	05/31/1995	Europe			ABSTRACT
Sta	5	EP 0391896	03/02/1994	Europe			
Sta	6	EP 0493437	08/02/1995	Europe			
Sta	7	EP 0513127	07/19/1995	Europe			
Sta	8	EP 0539522	12/30/1998	Europe			
Sta	9	EP 0553298	11/17/1994	Europe			
Sta	10	EP 0556256	08/30/1995	Europe			
Sta	11	EP 0587790	01/03/1996	Europe			
Sta	12	EP 0588897	02/28/1996	Europe			
Sta	13	EP 0605578	01/10/1996	Europe			
Sta	14	EP 0656206	06/07/1995	Europe			
Sta	15	EP 0658101	06/21/1995	Europe			
	16	JP 03038592	02/19/1991	Japan			

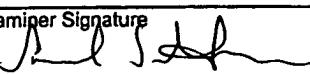
Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	17	Ahlneek et al., "The Molecular Basis of Moisture Effects on the Physical and Chemical Stability of Drugs in the Solid State", <u>Int. J. of Pharmaceuticals</u> , 62:87-95 (1990)
	18	Altenbach et al., "Ca ²⁺ Binding to Phosphatidylcholine Bilayers As Studied by Deuterium Magnetic Resonance. Evidence for the Formulation of a Ca ²⁺ Complex with Two Phospholipid Molecules" <u>Biochem.</u> 23:3913-3920 (1984)

Examiner Signature 	Date Considered <u>2/13/06</u>
--	--------------------------------

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Thomas E. Tarara et al.	
		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	19	Babincova et al., "Dextran Enhances Calcium-Induced Aggregation of Phosphatidylserine Liposomes: Possible Implications for Exocytosis", <i>Physiol. Res.</i> , 48(4):319-321 (1999)
	20	Buckton et al., "The Use of Gravimetric Studies to Assess the Degree of Crystallinity of Predominantly Crystalline Powders", <i>Int. J. of Pharm.</i> , 123:265-271 (1995)
	21	Buldt et al., "Neutron Diffraction Studies on Phosphatidylcholine Model Membranes", <i>J. Mol. Biol.</i> 123:673-691 (1979)
	22	Cevc, G., "Membrane Electrostatics" <i>Biochim. Biophys. Acta.</i> , 1031(3):311-382 (1990)
	23	Dellamary et al., "Hollow Porous Particles in Metered Dose Inhalers", <i>Pharm. Research</i> 17(2): 168-174 (2000)
	24	Duzgunes et al., "Studies on the Mechanism of Membrane Fusion. Role of Head-Group Composition in Calcium- and Magnesium-Induced Fusion of Mixed Phospholipid Vesicles" <i>Biochim. Biophys. Acta.</i> , 642:184-195 (1981)
	25	Ebara et al., "Interactions of Calcium Ions with Phospholipid Membranes" <i>Langmuir</i> , 10:2267-2271 (1994)
	26	Eisenberg et al., "Absorption of Monovalent Cations to Bilayer Membranes Containing Negative Phospholipids" <i>Biochem.</i> , 18(23):5213-5223 (1979)
	27	Goldbach et al., "Spray-Drying of Liposomes for a Pulmonary Administration I. Chemical Stability of Phospholipids", <i>Drug Develop Inc. Pharm.</i> , 19(19):2611-2622 (1993)
	28	Gordon et al., "Ideal Copolymers and the Second-Order Transitions of Synthetic Rubbers. I. Non-Crystalline Copolymers", <i>J. Appl. Chem.</i> , 2:493-500 (1952)
	29	Hancock et al., "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems", <i>J. of Pharm. Sci.</i> , 86(1):1-12 (1997)
	30	Hancock et al., "The Relationship Between the Glass Transition Temperature and the Water Content of Amorphous Pharmaceutical Solids", <i>Pharm Res.</i> , 11(4):471-477 (1994)
	31	Hauser et al., "Comparative Structural Aspects of Cation Binding to Phosphatidylserine Bilayers", <i>Biochim. Biophys. Acta.</i> , 813:343-346 (1985)
	32	Hauser et al., "Interactions of Divalent Cations with Phosphatidylserine Bilayer Membranes" <i>Biochem.</i> , 23:34-41 (1984)

Examiner Signature 	Date Considered 2/3/06
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	33	Huster et al., "Investigation of Phospholipid Area Compression Induced by Calcium-Mediated Dextran Sulfate Interaction", <i>Biophys. J.</i> , 77(2):879-887 (1999)
	34	Huster et al., "Strength of Ca(2+) Binding to Retinal Lipid Membranes: Consequences for Lipid Organization" <i>Biophys. J.</i> 89(6): 3011-3018 (2000)
	35	Jacobson et al. "Phase Transitions and Phase Separations in Phospholipid Membranes Induced by Changes in Temperature, pH, and Concentration of Bivalent Cations" <i>Biochem.</i> 14(1):152-161 (1975)
	36	Kwon et al., "Calcium Ion Adsorption on Phospholipid Bilayers-Theoretical Interpretation" <i>J. Jap. Oil Chem Soc.</i> 43(1):23-30 (1994)
	37	Lis et al., "Adsorption of Divalent Cations to a Variety of Phosphatidylcholine Bilayers", <i>Biochem.</i> 20:1771-1777 (1981)
	38	Lis et al., "Binding of Divalent Cations to Dipalmitoylphosphatidylcholine and Its Effect on Bilayer Interaction", <i>Biochem.</i> 20:1761-1770 (1981)
	39	Millqvist-Fureby et al., "Surface Characterisation of Freeze-Dried Protein/Carbohydrate Mixtures", <i>Int. J. Pharm.</i> 191:103-114 (1999)
	40	Millqvist-Fureby et al., "Spray-Drying of Trypsin - Surface Characterization and Activity Preservation", <i>Int. J. Pharm.</i> , 188:243-253 (1999)
<i>gla</i>	41	Mutterlein, et al., "New technology for generating inhalation aerosols—preliminary results with the piezoelectrical pocket-inhaler", <i>J. Aerosol Med.</i> , 1:231 (1988)
	42	Parasassi et al., "Calcium-Induced Phase Separation in Phospholipid Bilayers. A Fluorescence Anisotropy", <i>Cellular and Molecul. Bio.</i> , 32(3):261-266 (1986)
<i>26</i>	43	"Aerosols, Metered-Dose Inhalers, and Dry Powder Inhalers", <i>Pharmacopeial Forum</i> , 22(6): 3065 (1996)
	44	Reboiras, M.D., "Activity Coefficients of CaCl ₂ in the Presence of Dipalmitoylphosphatidylcholine-Phosphatidylinositol Vesicles in Aqueous Media", <i>Bioelectrochemistry and Bioenergetics</i> , 39:101-108 (1996)
	45	Roth et al., "Production of Hollow Spheres", <i>Paragonon Press</i> , Vol. 19, No. 7, pp. 939-942 (1998)
	46	Royall et al., "Characterisation of Mixture Uptake Effects on the Glass Transitional Behaviour of an Amorphous Drug Using Modulate Temperature DSC", <i>Int. J. Pharm.</i> , 192:39-46 (1999)

Examiner Signature 	Date Considered <i>2/3/06</i>
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16614-030001	Application No. 10/612,393
Information Disclosure Statement by Applicant (Use several sheets if necessary)		Applicant Thomas E. Tarara et al.	
(37 CFR §1.98(b))		Filing Date July 3, 2003	Group Art Unit 1616

Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner Initial	Desig. ID	Document	
	47	Satoh, Koichi, "Determination of Binding Constants of Ca ²⁺ , Na ⁺ , and Cl ⁻ Ions to Liposomal Membranes of Dipalmitoylphosphatidylcholine at Gel Phase by Particle Electrophoresis", Biochem. Biophys. Acta 1239:239-248 (1995)	
	48	Seddon, J.M., "Structure of the Inverted Hexagonal (H1 I) Phase, and Non-Lamellar Phase Transitions of Lipids", Biochem Biophys. Acta., 1031:1-69, in particular pp. 43-44 and 49-50 (1990)	
	49	Seelig, Joachim, "Handbook Met. - Ligand Interact. Biol. Fluids, Bioinorg. Chem., Section, Metal Ion Interaction with Lipids" pp. 698-706 (1995)	
	50	Shah et al., "The Ionic Structure of Sphingomyelin Monolayers", Biochem Biophys. Acta., 135:184-187 (1967)	
	51	Shavnin et al., "Cholesterol Affects Divalent Cation-Induced Fusion and Isothermal Phase Transitions of Phospholipid Membranes" Biochem Biophys Acta., 946:405-416 (1988)	
	52	Simha et al., "On a General Relation Involving the Glass Temperature and Coefficients of Expansion of Polymers", J. Chem. Physics, 37(5):1003-1007 (1962)	
	53	Sugisaki et al., "Calorimetric Study of the Glassy State. IV. Heat Capacities of Glassy Water and Cubic Ice", Bulletin of the Chem. Soc. Of Japan, 41:2591-2599 (1968)	
	54	Tatulian, S.A., "Binding of Alkaline-Earth Metal Cations and Some Anions to Phosphatidylcholine Liposomes", Eur. J. Biochem., 170:413-420 (1987)	
	55	Tatulian, S.A., "Evaluation of Divalent Cation Binding to Phosphatidylserine Membranes by an Analysis of Concentration Dependence Surface Potential", J. Colloid Interface Science, 175:131-137 (1995)	
	56	Verstraeten et al., "Effects of A1(3+) and Related Metals on Membrane Phase State and Hydration: Correlation with Lipid Oxidation", Arch. Biochem. Biophys., 375(2):340-346 (2000)	
	57	Whipps et al., "Growth of Calcium Monohydrate at Phospholipid Langmuir Monolayers", J. Cryst. Growth, 192:243-249 (1998)	
	58	Yamaguchi et al., "Adsorption of Divalent Cations onto the Membrane Surface of Lipid Emulsion" Colloids and Surface B: Biointerfaces, 5:49-55 (1995)	
	59	Zarif et al., "Amphotericin B Cochleates as a Novel Oral Delivery System for the Treatment of Fungal Infections", Proceedings of the International Symp. on Controlled Release Bioactive Materials., pp. 964-965 (1999)	

Examiner Signature 	Date Considered 2/3/06
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	